

# **Exhibit 11**

**From:** Zink, Donald <Donald.Zink@fda.hhs.gov>  
**Sent:** Tuesday, August 26, 2014 11:26 AM  
**To:** Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Poos, Mary <Mary.Poos@fda.hhs.gov>  
**Cc:** Fedorchak, Carol <Carol.Fedorchak@fda.hhs.gov>; Summers, Linda L <Linda.Summers@fda.hhs.gov>; Berndt, Susan <Susan.Berndt@fda.hhs.gov>  
**Subject:** FW: Manuscript clearance  
**Attach:** FDAMedwatchJournalArticle-8-25-2014.doc; Figure 1 - OEPklontz.jpg; Figure 2 - OEPklontz.jpg; Figure 3 - OEPklontz.jpg; ManuscriptClearanceFormKlontz.pdf

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This manuscript deals with adverse events and dietary supplements and thus falls under our "sensitive topics" clearance policy. The manuscript needs to be reviewed and cleared by Linda Katz and Mary Poos. By copy of this email, I am transmitting the manuscript to them for clearance.

Don Zink

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**From:** <Fedorchak>, Carol <[Carol.Fedorchak@fda.hhs.gov](mailto:Carol.Fedorchak@fda.hhs.gov)>  
**Date:** Tuesday, August 26, 2014 11:19 AM  
**To:** Linda Summers <[linda.summers@fda.hhs.gov](mailto:linda.summers@fda.hhs.gov)>, Karl Klontz <[karl.klontz@fda.hhs.gov](mailto:karl.klontz@fda.hhs.gov)>  
**Cc:** Donald Zink <[donald.zink@fda.hhs.gov](mailto:donald.zink@fda.hhs.gov)>, "Berndt, Susan" <[Susan.Berndt@fda.hhs.gov](mailto:Susan.Berndt@fda.hhs.gov)>  
**Subject:** FW: Manuscript clearance

Hi, Karl,

I am on detail to ORA so I am forwarding to Linda for assistance since manuscript clearance falls under SSAS. The SOP can be found here. <http://inside.fda.gov:9003/CFSAN/SeniorScienceAdvisor/FormsandResources/default.htm>

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**From:** Klontz, Karl C  
**Sent:** Tuesday, August 26, 2014 10:32 AM  
**To:** Fedorchak, Carol  
**Subject:** Manuscript clearance

Hell Carol,

May I ask for your assistance in obtaining clearance from the Center Director's level for the attached manuscript entitled, "The Role of Adverse Event Reporting in a U.S. Food and Drug Administration Response to a Multi-State Outbreak of Liver Disease Associated With a Dietary Supplement"?

The first attachment contains the manuscript along with its references and tables. It also contains the figures, but I have attached separately each of the 3 figures in files that were professionally done by our graphics staff. Finally, I have attached a copy of the manuscript clearance form that has been signed at the Office Director level for the Office of Analytics and Outreach.

The paper summarizes the role FDA assumed in the investigation of liver injuries sustained following ingestion of a dietary supplement called OxyElitePro. Much of the investigation took place during the government shutdown last year. During that time, I worked with CORE, Mr. Landa, and a skeletal crew here in CFSAN to review medical records and MedWatch forms.

This paper represents one of a trio that will be submitted for publication by FDA, CDC, and the Defense Department. Each agency has agreed to produce its own manuscript summarizing its activities during the outbreak. CDC's paper is making its way through internal clearance at CDC currently. I do not know the status of DoD's paper. In light of CDC's plan to submit its paper to a journal in the near-future, ideally, we would like to do in a time frame that is expeditious.

We are aiming to submit this manuscript to the American Journal of Preventive Medicine.

Since a number of authors are from CORE and one from CVM, the manuscript is being cleared by each of those two entities as well.

Please let me know if I may assist the clearance process in any manner, and thank you for your assistance.

